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PATENT APPLICATION
Attorney's Do. No. 1420-2

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Box Patent Application
Assistant Commissioner for Patents
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Enclosed for filing is a patent application under 37 CFR 1.53(b) of:

Inventor: David William House

For: **COCHLEAR IMPLANTS WITH A STIMULUS IN THE HUMAN
ULTRASONIC RANGE AND METHOD FOR STIMULATING A
COCHLEA**JC530 U.S. PTO
09/478136JC530 U.S. PTO
01/05/00

Enclosures:

- Specification (pages 1-8); claims (pages 9-10); abstract (page 11)
- 5 sheet(s) of drawings
- Declaration or Combined Declaration and Power of Attorney
 - Newly executed (original or copy)
- Information Disclosure Statement with Form PTO 1449
- Copies of references listed on attached Form PTO-1449
- Declaration(s) Claiming Small Entity Status
 - Independent Inventor (37 CFR 1.9(f) and 1.27(b))

CLAIMS AS FILED

For	Number Filed	Number Extra	Rate	Basic Fee
Total Claims	18-20	0	x \$ 9 =	0
Independent Claims	3-3	0	x \$ 39 =	0
TOTAL FILING FEE				\$380

- A check in the amount of \$380 to cover filing fee is enclosed.
- Any deficiency or overpayment should be charged or credited to deposit account number 13-1703. A duplicate copy of this sheet is enclosed.

Customer No. 20575

Respectfully submitted,

MARGER JOHNSON & McCOLLOM, P.C.

By

Gregory T. Kavounas
Gregory T. Kavounas
Registration No. 37,862

MARGER JOHNSON & McCOLLOM, P.C.
1030 S.W. Morrison Street
Portland, Oregon 97205
Telephone: (503) 222-3613

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant or Patentee: David William House

Serial or Patent No.: not yet known

Filed or Issued: filed herewith

For: **COCHLEAR IMPLANTS WITH A STIMULUS IN THE HUMAN ULTRASONIC RANGE AND METHOD FOR STIMULATING A COCHLEA**

DECLARATION CLAIMING SMALL ENTITY STATUS (37 CFR 1.9(f) and 1.27 (b)) INDEPENDENT INVENTOR

As a below-named inventor, I hereby state that I qualify as an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, to the Patent and Trademark Office with regard to the invention entitled

described in the

[x] specification filed herewith

[] application serial no. _____, filed _____,

[] patent no. _____, issued _____

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[] persons, concerns or organizations listed below*

*NOTE: Separate statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

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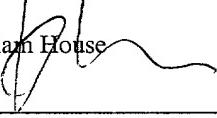
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Full name of sole or first inventor:

David William House

Inventor's signature:



12-30-1999

(Date)

5 **COCHLEAR IMPLANTS WITH A STIMULUS IN THE HUMAN
ULTRASONIC RANGE AND METHOD FOR STIMULATING A COCHLEA**

BACKGROUND OF THE INVENTION

1. Field of the invention

The present invention is related to the field of hearing aids, and more specifically to
10 the field of permanent cochlear implants for the hearing impaired.

2. Description of the related art

Hearing aids are often designed to amplify sound. These do not work, however, for patients with severe deafness because they cannot hear any sound, no matter how loud. For
15 such patients, an implant technology is used, which stimulates directly the cochlea of the human ear.

The implant technology is now described in more detail with reference to FIG. 1. A human pinna (outer portion of the ear) 20 is supported on tissue 22 of the patient's head. When a sound 24 in the audible range of 20 Hz to 20,000 Hz reaches the pinna 20, the sound
20 24 reaches the eardrum 28 through an opening 26 in the tissue 22, known as the ear canal 26. In a healthy person, the eardrum 28 in turn excites the cochlea 30 mechanically, through additional structures (bones of hearing; not shown). The cochlea 30 accordingly stimulates the hearing nerve 31. In a severely deaf person, however, the cochlea 30 does not produce nerve stimulations, and thus the hearing nerve 31 transmits nothing to the brain.

25 A cochlear implant has two main parts, an internal unit 32 and an external unit 50. The internal unit 32 is surgically implanted near the pinna 20 of the patient. The internal unit 32 has at least one electrode 34 that is coupled with the cochlea 30. The internal unit 32 includes an internal coil assembly 40 for electrically driving the electrode 34. The internal unit 32 also includes a magnet 42.

30 The external unit 50 also includes a magnet 52, for suspending the external unit 50 from the field of the magnet 42. The external unit 50 also includes a microphone and signal processing component 54, and an external coil assembly 56. When the sound 24 reaches the microphone and signal processing component 54, the component 54 generates a signal which drives the external coil assembly 56. The signal is then inductively coupled ("injected") into
35 the internal coil assembly 40.

Referring to FIG. 2, component 54 includes an oscillator 57, which generates a carrier analog signal. A volume control unit 58 is preferably implemented by an adjustable gain amplifier that amplifies the analog carrier signal. Adjusting the volume control unit 58 determines how much overall sound sensation, also known as percept, will reach the patient.

- 5 In an older implementation of this cochlear implant, the amplified analog carrier signal is input into an amplitude modulator 60, to be amplitude modulated by the received sounds.

Component 54 also includes a microphone 62 with its associated circuitry, a preamplifier 64, and a band pass filter 66. The band pass filter 66 allows to pass only those frequencies of the preamplified electrical signal that correspond to sound in the range of 200
10 Hz - 4000 Hz. The band pass filter 66 discards the signal corresponding to sound 24 that corresponds to the rest of the frequencies, that is, anything outside the frequency range of the band pass filter 66.

The filtered signal from band pass filter (BPF) 66 is input in a modulation control unit 68. The modulation control unit 68 thus uses the filtered signal to modulate the pre-amplified analog carrier signal in modulator 60. The modulator 60 output the modulated signal to an output amplifier 70. Thus amplified, the modulated signal is input into external coil assembly 56 of FIG. 1.

As described immediately above, the prior art limits how much sound percept can be delivered to the patient. This is now explained in more detail.

20 Referring also to FIG. 3, the interrelationship of the chosen frequencies is placed in perspective. A healthy ear can hear sounds between 20 Hz and 20 kHz (thus these are called the sonic, or hearable frequencies), which is denoted as a sonic range 78. The frequencies important to the understanding of speech belong within a speech range 80, reaching up to a frequency of 8 kHz. The carrier analog signal is denoted in FIG. 3 as an arrow 76, and is at a
25 frequency of 16 kHz, which is within the sonic range 78.

Experiments using the above system showed that sound frequencies higher than 4,000 Hz sounded unclear to the user. Accordingly, the prior art included the band pass filter 66 (seen in FIG. 2), which has a BPF range 86 (seen in FIG. 3).

30 The result is that the prior art system only works for sounds within the BPF range 86 of the band pass filter 66. The prior art has rationalized this by concluding that the important portion of the sensitivity range of the human ear 78 is the portion where the speech range 80 belongs, and that further, the most important portion of the speech range 80 is found at 4,000 Hz and below.

Patients desire to be able to hear speech at the frequency higher than 4,000 Hz, and other sounds at frequencies higher than 8,000 Hz, just like healthy people.

BRIEF SUMMARY OF THE INVENTION

5 The present invention improves on the limitations of the prior art.

Generally, the present invention provides a cochlear implant system. The system includes an internal unit and an external unit. The internal unit includes at least one electrode for coupling with the patient's cochlea, and an internal (implanted) coil to inductively drive the electrode. The external unit includes a microphone for producing electrical signals in response to external sounds. In one embodiment of the invention, the external unit also includes an oscillator for generating an electrical analog carrier signal, and a modulator for modulating the carrier signal with the sound signals to generate a modulated signal. An external coil magnetically couples the modulated signal to the internal coil.

10 15 The analog carrier signal has a frequency in the ultrasonic human range, i.e. greater than 20,000 Hz, such as 32,000 Hz or 80,000 Hz. This higher frequency results in clearer rendering of sounds, and a higher frequency range of rendered sounds.

The foregoing and other objects, features and advantages of the invention will become more readily apparent from the following detailed description of a preferred embodiment, which proceeds with reference to the drawings.

20

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a partial section view of a patient using a prior implant technology.

FIG. 2 is a block diagram of a microphone and signal processing component 54 of an external unit 50 of the prior implant technology of FIG. 1.

25 FIG. 3 is a graph showing the relative frequency ranges of the sensitivity of the human ear, speech, and a carrier frequency of an oscillator and a band pass filter in FIG. 2.

FIG. 4 is a partial section view of the patient using a cochlear implant system made according to an embodiment of the present invention.

30 FIG. 5 is a block diagram for a circuit of a driver for a cochlear implant system made according to an embodiment of the present invention.

FIG. 6 is data showing the frequency of a carrier according to an embodiment of the present invention relative to the ranges of the sensitivity of the human ear and of speech.

FIG. 7 is the flowchart for illustrating a method according to an embodiment of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT(S)

As has been mentioned, the present invention provides a cochlear implant system, a driver for cochlear implant system, and a method for stimulating a cochlea. The invention is now described with reference to FIGs. 4-7.

5 Referring to FIG. 4, a cochlear implant system 100 of the invention is described in detail. The cochlear implant system 100 includes an internal unit 132 that is surgically implanted near the pinna 20 of the patient, and preferably close to the skin 22. The internal unit 132 has at least one active electrode 134 that is inserted into the cochlea 30 through hole 36. In addition, a second electrode (not shown) is optionally implanted in other nearby tissue,
10 and used to provide a reference voltage to the active electrode 134.

The internal unit 132 includes an internal coil assembly 140 for electrically driving the electrode 134. In the preferred embodiment, the internal coil assembly 140 has two ends, one coupled to the active electrode 134, and the other coupled with the reference electrode (not shown). An advantage of the implant technology is that the internal coil assembly 140 can be driven externally. As such, there is no need for a battery, which would require changing after sometime. This permits implanting permanently the internal unit 132, with its sensitive contact of the cochlea 30.
15

20 The internal unit 132 also includes a magnet 142, which can be a simple magnet, or a more sophisticated magnet arrangement. The magnet 142 is so oriented that its strongest field is located outside the head, in a preferential direction (e.g., north vs. south vertically).

25 The cochlear implant system 100 of the invention further includes the driver 150, which is also known as an external unit 150. The driver 150 is for driving the implanted internal coil assembly 140, and therefore driving the electrode 134. The actual size of driver 150 can be as small in diameter as a U.S.A. penny, or even smaller. In FIG. 4, the external unit 150 is shown larger only for clarity.

In another embodiment, the invention provides only the driver 150, which would be used for patients who have already been implanted with cochlear implant systems using the prior art, which will thus perform better.

30 The external unit 150 is suspended in a spatial relation to the internal unit 132 by any means known in the art. Preferably, the external unit 150 includes a magnet 152 that interacts with the field of the magnet 142. The magnets 152 and 142 are thus used to suspend the external unit 150 on the tissue 22 of the patient, without any further support. Preferably, the magnets are arranged such that their polarities permit the driver 150 to be attached to a single, well-defined place on the tissue 22. If, however, the external unit 150 is suspended in a

different way, then there is no need for either the internal unit 132 to have a magnet 142, or for the driver to have a magnet 152.

The external unit 150 includes a microphone and signal processing component 154, and an external coil assembly 156. The external unit 150 preferably includes a battery, which
5 can be replaced as needed. When the sound 24 reaches the microphone and signal processing component 154, the component 154 generates a signal for driving the external coil assembly 156. The generated signal is an analog signal that is also known as electrical sound signal. The generated signal is thus coupled into the internal coil assembly 140. In other words, the
10 external coil assembly 156 forms a transformer with the internal coil assembly 140, and inductively drives it.

Referring to FIG. 5, the microphone and signal processing component 154 is described in detail. In one embodiment, component 154 includes an oscillator 157, which generates a carrier analog signal. The analog signal is continuous, and preferably sinusoidal. This is not limiting, however. The carrier analog signal of the invention can be triangular shaped, sawtooth shaped, etc. Such other shapes introduce additional, secondary carrier frequencies.
15

Importantly for the present invention, the carrier analog signal from oscillator 157 has a frequency greater than 20 kHz, i.e. it is outside the range of normal human hearing. One good operating value is 32 kHz. Higher values, such as 80kHz, also work very well. The significance of this choice will be appreciated in view of the description pertaining to FIG. 6, later in this document.
20

Continuing to refer to FIG. 5, a volume control unit 158 is preferably implemented by an adjustable gain amplifier that amplifies the analog carrier signal. Adjusting the volume control unit 158 determines how much total sound percept will reach the patient. The
25 amplified analog carrier signal is input into a modulator 160, to be amplitude modulated by the received sounds.

In one embodiment of the invention, modulator 160 is an amplitude modulator. In another embodiment of invention, modulator 160 is a frequency modulator. Stimulation by means of analog signals in the ultrasonic range can also be done directly, or in other ways, to
30 provide the patient with a percept of sound.

Component 154 also includes a microphone 162 with its associated circuitry, and an optional preamplifier 164. The microphone 162 outputs an electrical signal responsive to the sounds 24 it receives. The preamplifier 164 amplifies the electrical signal of the microphone 162.

It should be noted that is no need for a band pass filter, such as band pass filter 66 of FIG. 2. Even if one is included, its upper limit can be much higher than that of the prior art, thus permitting a wider range of frequencies to be presented or perceived.

The signal from the preamplifier 164 is input in a modulation control unit 168. The 5 modulation control unit 168 thus uses the signal to modulate the preamplified analog carrier signal in modulator 160. The modulator 160 outputs the modulated signal to an output amplifier 170. Thus amplified, the modulated signal is input into the external coil assembly 156 of FIG. 4.

The superiority of the present invention is now explained by first analyzing further the 10 weakness of the prior art system, as explained in FIG. 3. All the prior art globally adopted the carrier 76 to be at 16 kHz, within the sensitivity of human ear range 78. The prior art references universally treat the value of 16 kHz as an undisputed optimum.

The choice of the frequency of the carrier 76 imposes an upper limit as to the 15 frequency that can be transmitted clearly. This results from the Nyquist limit. In other words, the carrier 76 samples the speech at its own frequency of 16 kHz. The higher the frequency of the sampled sound, the less clearly it will be rendered. For a frequency of 16 kHz, the Nyquist limit turns out to be 1/4 of that, in other words 4 kHz. Indeed, the users of the prior art system of FIG. 1 found sounds having a frequency of higher than 4 kHz confusing.

Referring now to FIG. 6, the invention proposes that there is no reason for the carrier 20 174 produced by the oscillator 157 to be within the sound sensitivity frequency range of the human ear, or in the sonic range 78. As such, the carrier 174 is chosen to have a frequency of greater than 20 kHz. As can be seen from observing the ordinary human range 78, these frequencies for the carrier 174 belong in the human ultrasonic range.

It will be appreciated how the Nyquist limit permits a much higher range for the 25 system of the present invention. In the embodiment of FIG.s 4, 5 and 6, the carrier frequency is 32 kHz, with a Nyquist limit of 8 kHz. This includes the entire range of speech 80, without limiting it, as the prior art did. It will now also be clear that, to match the sensitivity of the healthy human ear, the system of the invention should have a carrier frequency of (4 x 20 30 kHz) 80 kHz.

There is no need to stop there, either. A higher carrier frequency will permit the user to hear frequencies higher than any human has ever heard before. This can be extended to people who have no hearing deficit in the first place.

Other technical details for implementing the invention can be gleaned from the following publications, the disclosure of which is hereby incorporated herein by reference.

These are:

- U.S. Patent Re. 32,947;
- 5 • Design and Function: A Physical and Electrical Description of the 3M House Cochlear Implant System, Fretz & Fravel, Ear and Hearing, Vol. 6, No. 3 Supplement, pp. 14S - 19S, 1985;
- DESIGN AND FUNCTIONING OF THE SINGLE - ELECTRODE COCHLEAR IMPLANT, Danley & Fretz, pp. 21-26;
- 10 • COCHLEAR IMPLANT SYSTEM, Series 7700 House Design, Manual for Audiologists: Device Fitting and Adjustment, 3M, 1985.

Referring to FIG. 7, a method according to the invention is now described for stimulating the cochlea in response to sound.

According to box 210, an electrical signal, also known as an electrical sound signal, is generated in response to the sound. This can be accomplished with a microphone, and associated circuitry.

According to box 220, an electrical analog carrier signal is generated having a frequency of greater than 20 kHz. This can be accomplished with an oscillator. The frequency can be 21 kHz, 32 kHz, 80 kHz, or whatever frequency is deemed suitable for the desired application.

According to box 230, the carrier signal is modulated with the sound signal to generate a modulated signal. Modulating can be by amplitude modulation or frequency modulation.

According to box 240, the modulated signal is applied to an electrode that is coupled with the cochlea.

In this description numerous details have been set forth in order to provide a more thorough understanding of the invention. A person skilled in the art will be able to practice the present invention in view of the present description and the incorporated references. In other instances, well-known features have not been described in detail in order not to obscure unnecessarily the invention.

The inventor regards the subject matter of the invention to include all combinations

and sub-combinations of the various elements, features, functions and/or properties disclosed herein. While the invention has been disclosed in its preferred form, the specific embodiments thereof as disclosed and illustrated herein are not to be considered in a limiting sense. Indeed, it should be readily apparent to those skilled in the art in view of the present description that the invention can be modified in numerous ways.

The following claims define certain combinations and sub-combinations of these elements, which are regarded as novel and non-obvious. Additional claims for other combinations and sub-combinations of features, functions, elements and/or properties may be presented in this or in a related document.

CLAIMS

The invention claimed is:

- 1 1. A method for stimulating a human cochlea in response to a sound, comprising:
2 generating an electrical sound signal in response to the sound;
3 generating an electrical analog carrier signal having a frequency greater than 20 kHz;
4 modulating the carrier signal with the sound signal to generate a modulated signal;
5 and
6 applying the modulated signal to an electrode that is coupled with the cochlea.

- 1 2. The method of claim 1, wherein modulating is by amplitude modulation.

- 1 3. The method of claim 1, wherein modulating is by frequency modulation.

- 1 4. The method of claim 1, wherein the electrical analog carrier signal has a
2 frequency of at least 32 kHz.

- 1 5. The method of claim 4, wherein modulating is by amplitude modulation.

- 1 6. The method of claim 4, wherein modulating is by frequency modulation.

- 1 7. A cochlear implant system for a patient's cochlea comprising:
2 at least one electrode for coupling with the patient's cochlea;
3 an internal coil for implanting in the patient to drive the electrode;
4 a microphone for outputting electrical sound signals in response to external sounds;
5 an oscillator for generating an electrical analog carrier signal having a frequency
6 greater than 20 kHz;
7 a modulator for modulating the carrier signal with the sound signals to generate a
8 modulated signal; and
9 an external coil for magnetically coupling the modulated signal to the internal coil.

- 1 8. The system of claim 7, wherein the modulator is an amplitude modulator.

1 9. The system of claim 7, wherein the modulator is a frequency modulator.

1 10. The system of claim 7, wherein the electrical analog carrier signal has a
2 frequency of at least 32 kHz.

1 11. The system of claim 10, wherein the modulator is an amplitude modulator.

1 12. The system of claim 10, wherein the modulator is a frequency modulator.

1 13. A driver for driving an at least partially implanted cochlear implant system
2 having at least one electrode coupled with the patient's cochlea and an internal coil for
3 driving the electrode, the driver comprising:

4 a microphone for receiving external sounds and outputting a corresponding electrical
5 sound signal;

6 an oscillator for generating an electrical analog carrier signal having a frequency
7 greater than 20 kHz;

8 a modulator for modulating the carrier signal with the sound signal to generate a
9 modulated signal; and

10 an external coil for coupling the modulated signal to the internal coil.

1 14. The driver of claim 13, wherein the modulator is an amplitude modulator.

1 15. The driver of claim 13, wherein the modulator is a frequency modulator.

1 16. The driver of claim 7, wherein the electrical analog carrier signal has a
2 frequency of at least 32 kHz.

1 17. The driver of claim 16, wherein the modulator is an amplitude modulator.

1 18. The driver of claim 16, wherein the modulator is a frequency modulator.

**COCHLEAR IMPLANTS WITH A STIMULUS IN THE HUMAN
ULTRASONIC RANGE AND METHOD FOR STIMULATING A COCHLEA**

5

ABSTRACT

A cochlear implant system for a patient's cochlea includes an external processor and an implanted internal unit. The internal unit includes one electrode for inserting in the patient's cochlea, and an internal coil for driving the electrode. The external processor 10 includes a microphone for outputting electrical sound signals in response to ambient or other sounds, an oscillator for generating an electrical analog carrier signal, and a modulator for modulating the carrier signal with the sound signals to generate a modulated signal. An external coil couples magnetically the modulated signal to the internal coil. The analog carrier signal has a frequency in the ultrasonic human range, i.e. greater than 20 kHz, such as 15 32 kHz or 80 kHz. This sampling at higher frequency results in clearer rendering of sounds, and a higher frequency range of rendered sounds.

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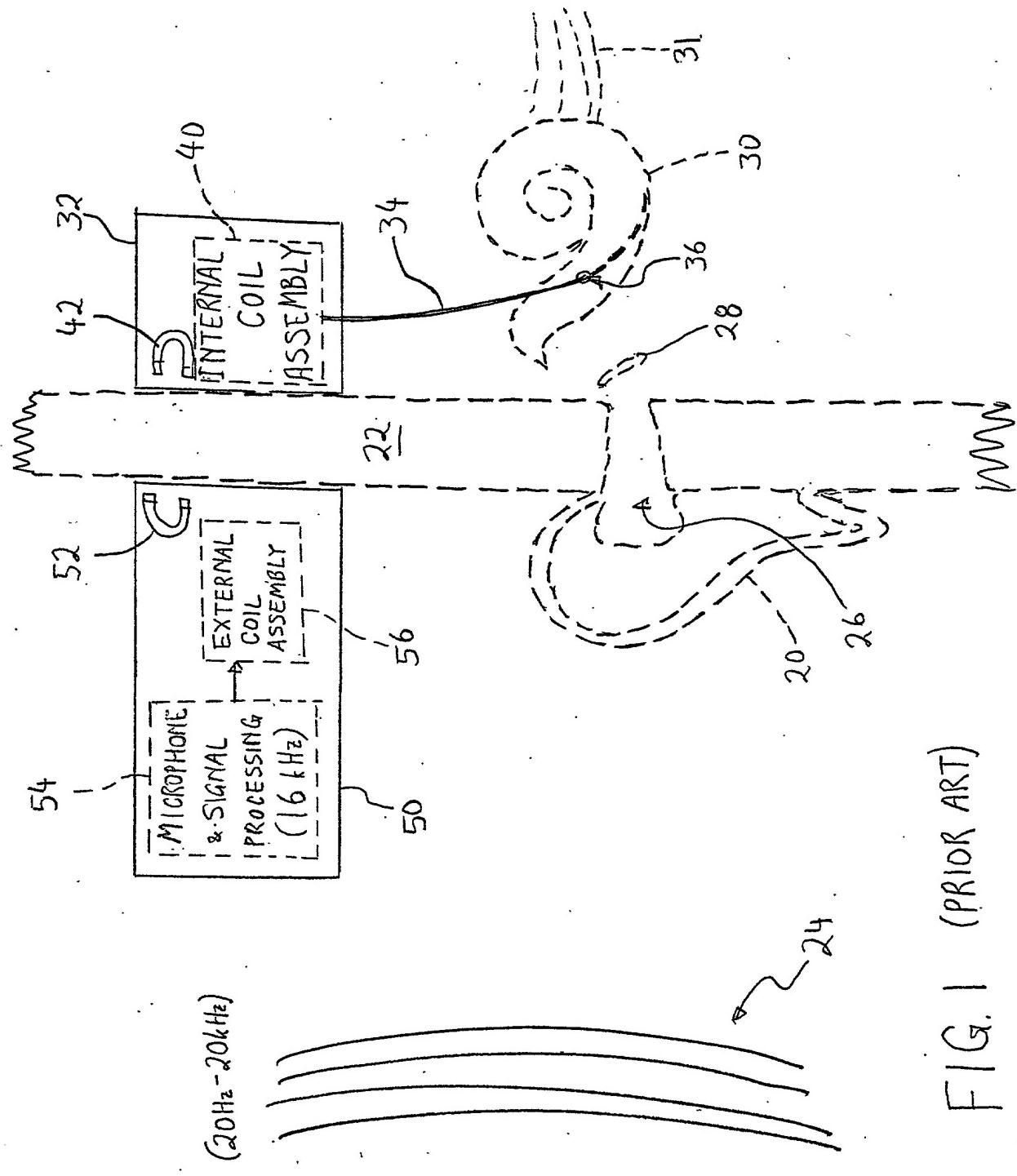


FIG. 1 (PRIOR ART)

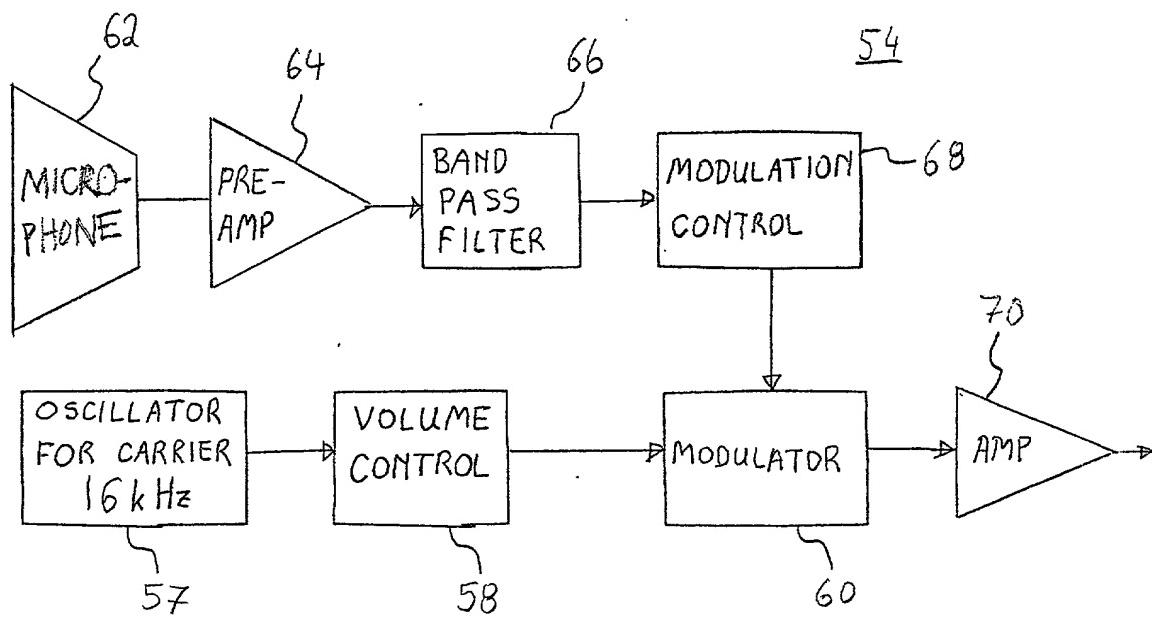


FIG. 2 (PRIOR ART)

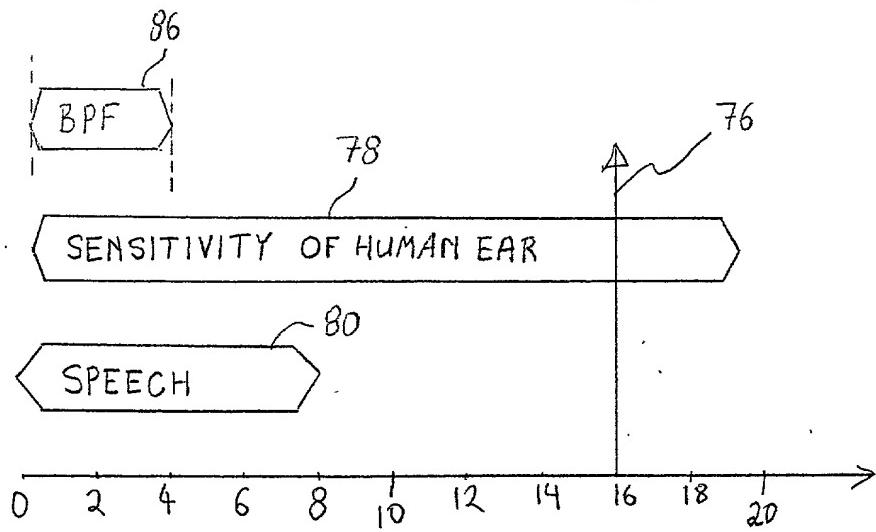


FIG. 3 (PRIOR ART)

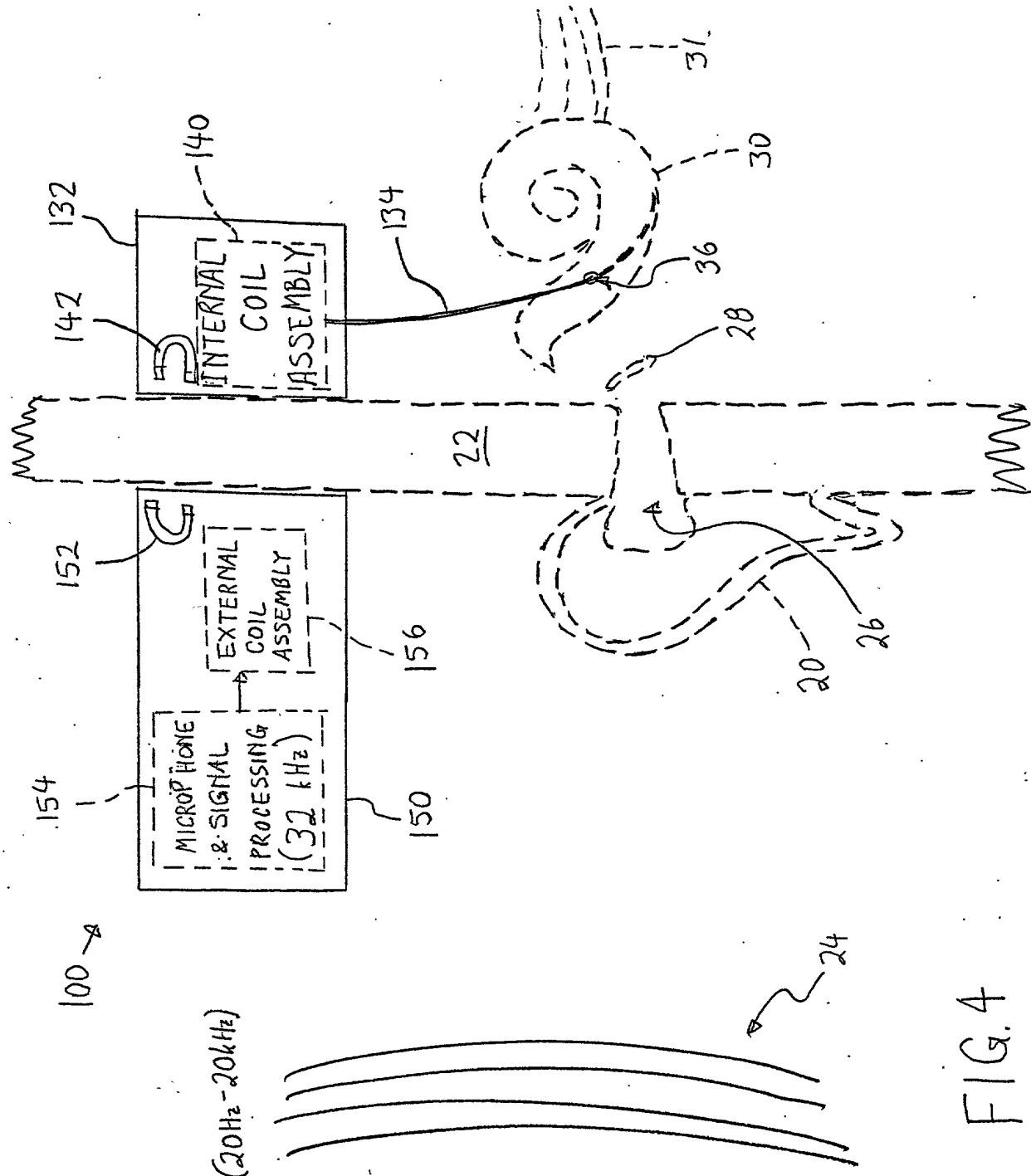


FIG. 4

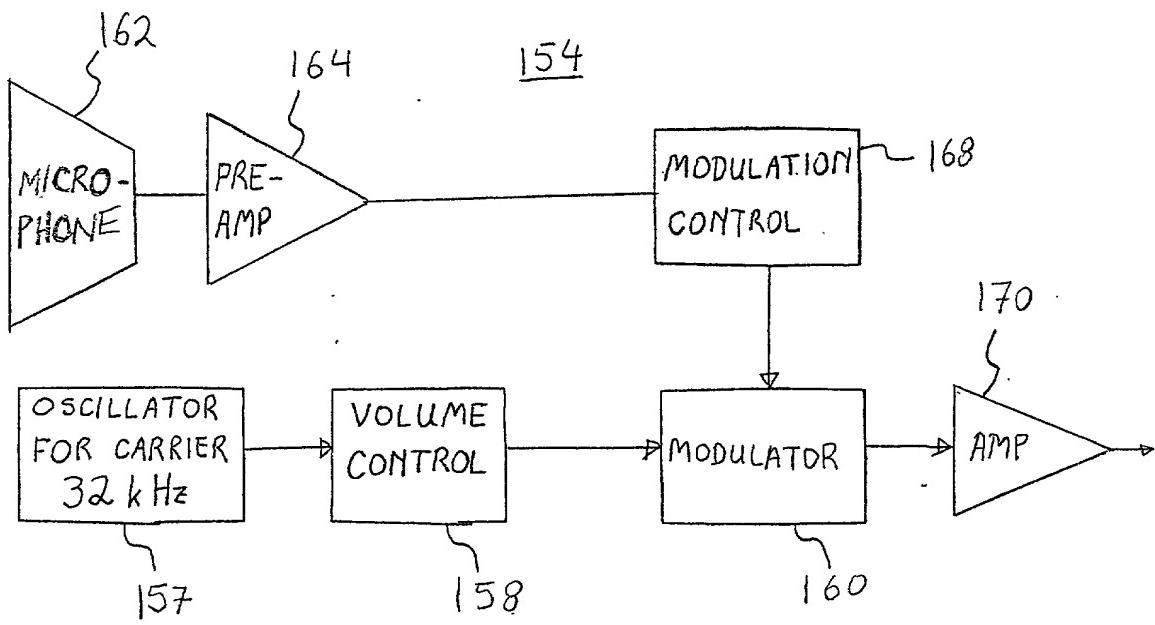


FIG. 5

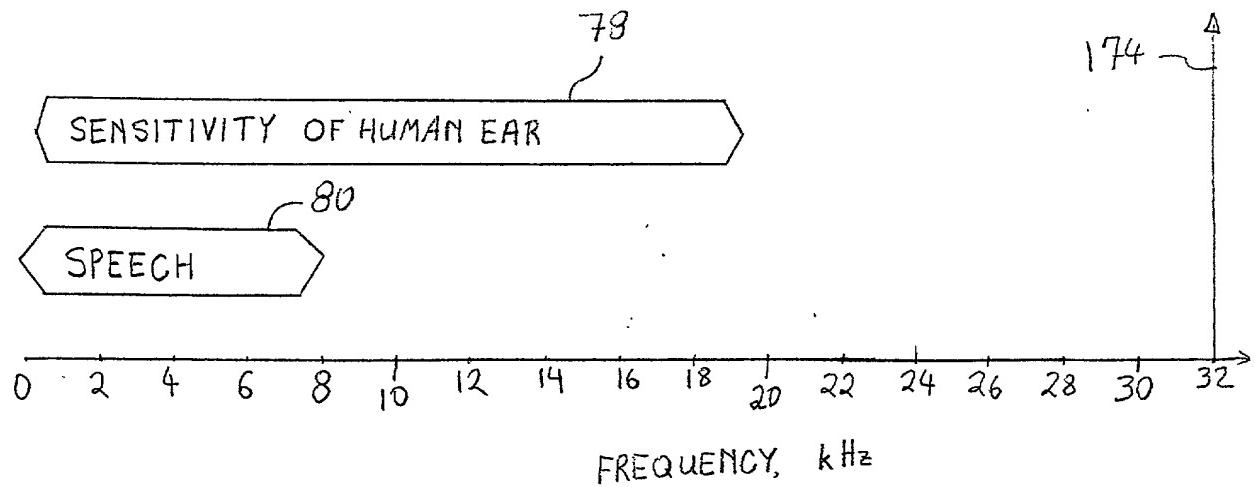


FIG. 6

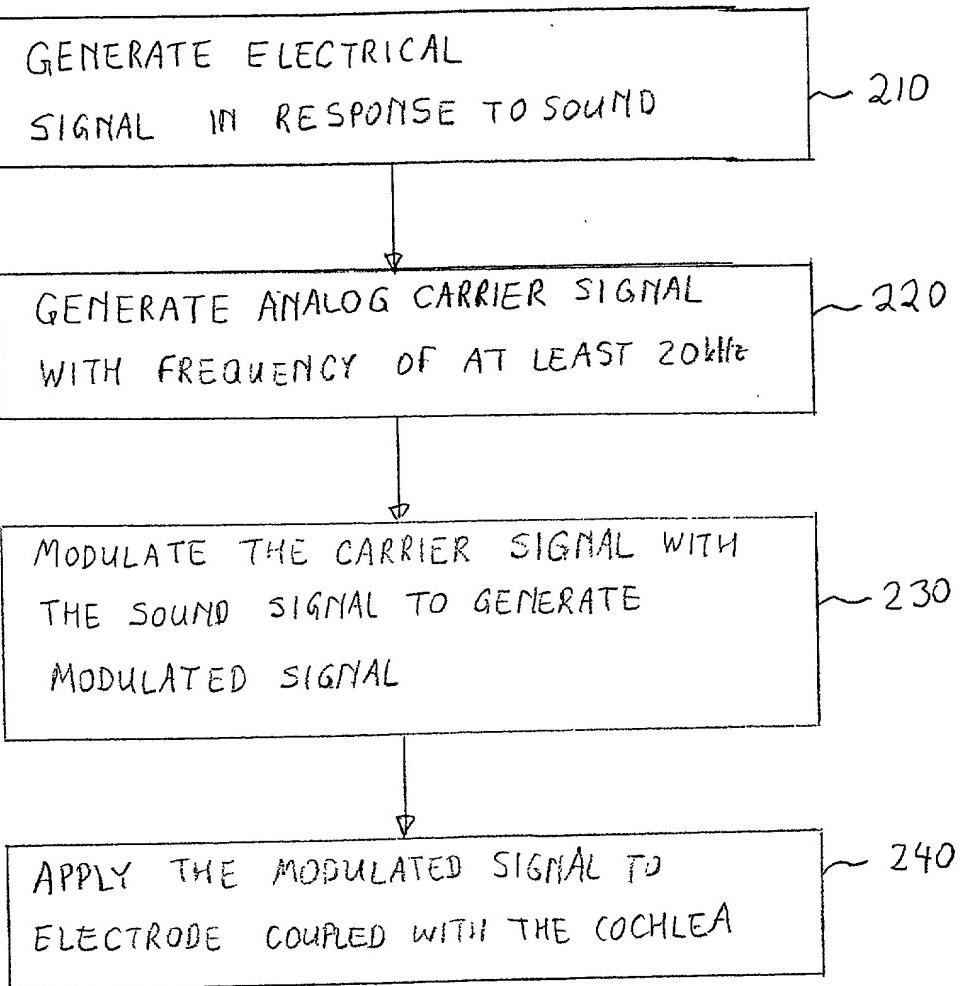


FIG. 7

PATENT APPLICATION
Attorney Docket No. 1420-2

COMBINED DECLARATION AND POWER OF ATTORNEY
FOR PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled **COCHLEAR IMPLANTS WITH A STIMULUS IN THE HUMAN ULTRASONIC RANGE AND METHOD FOR STIMULATING A COCHLEA**, the specification of which:

- [x] is attached hereto.
[] was filed on _____ as Application No. _____
[] and was amended on _____ (if applicable)
[] with amendments through _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the patentability of this application in accordance with Title 37, Code of Federal Regulations, Sec. 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, Sec. 119 (a)-(d) or §365(b) of any foreign application(s) for patent or inventor's certificate, or §365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)	Claiming Priority?			
(Number)	(Country)	(Day/Month/Year Filed)	[] Yes	[] No

I hereby claim the benefit under Title 35, United States Code, Sec. 119(e) of any United States provisional application listed below:

Provisional Application No.	Filing Date
_____	_____

I hereby claim the benefit under Title 35, United States Code, Sec. 120 or §365(c) of any PCT international application designating the United States of America listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35,

United States Code, Sec. 112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, Sec. 1.56 which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

(Application No.)

(Filing Date)

(Status) (patented, pending, abandoned)

I hereby appoint the following attorneys to prosecute the application, to file a corresponding international application, to prosecute and transact all business in the Patent and Trademark Office connected therewith:

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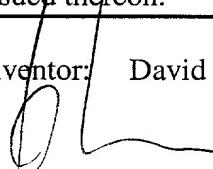
<u>Attorney Name</u>	<u>Registration No.</u>
Jerome S. Marger	26,480
Alexander C. Johnson, Jr.	29,396
Alan T. McCollom	28,881
James G. Stewart	32,496
Glenn C. Brown	34,555
Stephen S. Ford	35,139
Gregory T. Kavounas	37,862
Scott A. Schaffer	38,610
Joseph S. Makuch	39,286
James E. Harris	40,013
Graciela G. Cowger	42,444
Ariel Rogson	43,054
Craig R. Rogers	43,888

Direct all telephone calls to Gregory T. Kavounas at (503) 222-3613 and send all correspondence to:

MARGER JOHNSON & MCCOLLOM, P.C.
1030 S.W. Morrison Street
Portland, Oregon 97205

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole or first inventor: David William House

Inventor's signature: 

12.30.1999
(Date)

Residence: Aurora, OR U.S.A.

Citizenship: United States

Post Office address: 23022 Yeary Lane N.E., Aurora, OR 97002